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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/883,112	06/14/2001	Frederick F. Becker	UTXC:626US/MCB	7970

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EXAMINER	
DO, PENSEE T	
ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 08/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 10/03)

Office Action Summary	Application No.	Applicant(s)	
	09/883,112	BECKER ET AL.	
	Examiner	Art Unit	
	Pensee T. Do	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18,24-31,33-39 and 41* is/are pending in the application.

4a) Of the above claim(s) *1-18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18,24-31 and 33-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-18, 24-31, 33-39, 41* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry & Claims Status

The amendment filed on February 21, 2006 has been acknowledged and entered.

Claims 1-18, 24-31, 33-39, 41 are pending.

Claims 1-18 are withdrawn from further consideration.

Claims 24-31, 33-39 and 41 are being examined.

Withdrawn Rejection(s)

Rejections under 102 and 103 by Xu are withdrawn herein.

Maintained Rejection(s)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 36-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ewart et al. (US 5,922,537) in view of Parton et al. (US 5,653,859).

Ewart teaches an assay method, sandwich, indirect, competitive or direct assay, using reporter particles such as dielectric particles (see col. 4, lines 6-14). The core particles can be made from a wide variety of inorganic materials including metals such as gold, silver, platinum (see col. 5, lines 17-26). The particle core can be encapsulated in a polymer such as polystyrene (see col. 7, lines 20-30). The dielectric particles can

be engineered to have one or more dielectric properties or paramagnetic properties and phosphorescent properties (see col. 11, lines 7-13). In the assay, the target analyte is contacted with the reporter particles linked to a ***recognition molecule*** (linking element) that specifically binds the target analyte. Detection is performed by comparison of the dielectric constant of unbound dielectric particles/labels and that of the complexed dielectric particles/labels using a biosensor to measure those properties. (see col. 4, lines 53-65). The dielectric particles/labels contributes the dominant dielectric constant (second dielectric property) in the complex analyte-recognition molecule-dielectric label (see col. 14, lines 33-38). The dielectric property of an unbound dielectric label is the first dielectric property. The recognition molecule/linking element comprises of antibody, hormone, antigen, etc. (see col. 7, lines 54-65). The sample is bodily fluid such as blood (see col. 4, lines 49-51). Ewart also teaches that the dielectric particles/labels move in an electrophoretic field when being applied in a separation method (see col. 11, lines 27-31). Trapping is performed when the particles captures the analyte. Sorting is the same as separating and purification.

However, Ewart fails to teach manipulation by dielectrophoresis; a method wherein the sample comprises water, food, food processing, food distribution, mineral, or ore; admixing with the sample an engineered microparticle having a first dielectric property; associating the engineered particle with a target analyte to form a complex having a second dielectric property and detecting the complex by distinguishing between the first and second dielectric properties using one or more impedance sensors.

Parton teaches a method wherein a microparticle including an oligonucleotide or synthetic oligonucleotide analogue as a capture probe (linking moiety) bound to the surface of a polymer bead and having a sequence complementary to that of an expected amplification procedure product. A label comprising a traveling wave field migration (TWFW) labeling moiety bound to a second oligonucleotide or oligonucleotide analogue sequence complementary to the second region of the ligand nucleic acid sequence is employed. The microparticles and the label may be added to the product of the amplification reaction before or after any working up of the reaction mixture to separate the amplification products. The TWFM properties (second dielectric property) of the microparticle/amplification product/label ternary complex may then be observed and distinguished from those of the microparticles alone on the basis of different dielectric properties. The microparticle alone having a first dielectric property. If the oligonucleotides/target ligands are labeled with a “dielectric” marker, they can be separated on the basis of their dielectric properties. This may be achieved by using different migration frequencies, or selective electrode arrays. (see col. 9, line 25-col. 10 line 15; fig. 11, 1-3). The traveling wave field migration is the same as traveling wave dielectrophoresis. (see col. 2, lines 9-12). The label dielectric particles may comprise a second linking moiety carried by the label. The label is a fluorophore, a chromaphore or a micro-organism, a metal particle, a polymer bead or a magnetic particle. For use in connection with TWFM measurements, the label has dielectric properties and is capable of acquiring a significant surface charge. A preferred material is colloidal gold, which is easily bound to antibodies to form a label. (see col. 3, lines 34-60). The target

analyte may be a toxin present as a contaminant in a foodstuff. (see col. 8, lines 56-57). Detection is by electrical impedance, capacitance or inductance (see col. 8, lines 6-20). Thus, it is inherent that impedance sensors are being used.

It would have been obvious to one of ordinary skills in the art to use dielectrophoresis force or TWFM to separate target ligands as taught by Parton in the method of Ewart since these two references teach a separation method using dielectric particles as labels. Since Ewart teaches using particles with dielectric properties, it would have been obvious to use dielectrophoresis to separate these particles as taught by Parton because dielectrophoretic separation provides an efficient, reliable, nondisruptive, and automatable method for the separation of moieties in a sample based on their dielectric properties. Regarding claim 38, the sample comprising of food, water, food processing etc, since Ewart teaches, in col. 1, lines 32-35, that detection of analyte in a sample may be indicative of a particular condition in microorganism and higher life forms including animals and humans, one of ordinary skills in the art would find it obvious to detect analytes such as toxin from foodstuff taught by Parton or analytes from a variety of sample sources such as food, water because food and water contain microorganisms and food such as meat products are sources from animals. It would also have been obvious to one of ordinary skills in the art to use the impedance sensors as a detection means taught by Parton in the method of Ewart for detecting different dielectrophoretic properties of the particles since impedance sensors is means for distinguishing the different dielectric properties of the particles in assay application

such as target analyte such as a drug or a antibody for certain virus or bacteria which has been complexed with the dielectric microparticle for diagnostic advantages.

New Grounds of Rejection

Claim Rejections - 35 USC § 103

Claims 24-31, 33-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ewart in view of Parton as applied to claims 36 above, and further in view of Vo-Dinh (6,219,137).

Ewart and Parton have been discussed above. Moreover, regarding claim 41, since Parton teaches applying traveling-wave electric fields at various frequencies on electrode array (see col. 9, lines 24-col. 10, line 15), it is inherent that an AC electric field is applied because an ideal traveling-wave field is characterized by the distribution of the phase values of AC electric field components, being a linear function of the position of the particle. A traveling wave electric field can be established by applying appropriate AC signals to the electrodes.

However, Ewart and Parton fail to teach that the insulating layer (polymeric coating) comprises one or more self-assembled monolayer layers.

Vo-Dinh teaches a nanoprobe comprising a metallic system, which provides the Surface Enhanced Raman Spectroscopy (SERS) effect, and a chemical or biological system, which provides selective binding within a cell. The nanoprobe has a metallic core, which may be magnetic or electrically charged materials. For example, the core may be solely metallic material or a non-metallic material with a metallic coating. The core has an external coating formed of a polymer, a biological material (antibody,

enzyme, or DNA) or biometric material. A nanoprobe has specific receptors. Multiple nanoprobes can be used in high throughput screening for drug detection or medical diagnostics. (see col. 2, lines 43-63). The metallic core or surface can be coated with a monolayer of thiols for binding DNA oligonucleotides or peptide nucleic acids because thiols are known to strongly chemisorb to gold and silver surfaces to form monolayers that possess supra molecular properties. (see col. 5, lines 37-46).

It would have been obvious to one of ordinary skills in the art to modify the particles of Ewart and Parton so that they comprise a coating of thiols for attaching DNA as taught by Vo-Dinh since theses references teach coating metallic particle/core with a thin film or monolayer, and attaching DNA to the microparticles. Since the specification teaches that the self-assembled monolayer is thiols, and Vo-Dinh teaches thiols, such thiols in Vo-Dinh would self-assemble as a monolayer on gold/metallic surface.

Response to Arguments

Applicant's arguments filed February 21, 2006 have been fully considered but they are not persuasive.

Regarding the 103 rejection for claim 36, Applicants argue that Parton fails to teach admixing with a sample an engineered microparticle having a first dielectric property or associating an engineered microparticle with a target analyte to form a complex having a second dielectric property.

Parton teaches (col. 9, lines 25-col. 10, line 15, fig. 11, 1-3) that the TWFM properties (second dielectric properties) of the microparticle/amplification product/label

ternary complex is observed and distinguished from those of the microparticle alone on the basis of different dielectric properties. This passage alone satisfies the missing steps of claim 36. Ewart teaches that detection is performed by comparison of the dielectric constant of unbound dielectric particles/labels and that of the complexed dielectric particles/labels using a biosensor to measure those properties (see col. 4, lines 53-65). Thus, since Ewart teaches detection by comparison of the dielectric constant of unbound dielectric particles and that of the complexed, and Parton also teaches distinguishing the dielectric properties of the complex and that of the dielectric particle alone, the complex has a dielectric property different from that of the unbound dielectric particle. In order to form a complex, a step of associating the microparticle and the target analyte must be performed. This is inherently taught in the references. The complex must have a different dielectric property in order for it to be distinguished from the first dielectric property or the dielectric property of the unbound dielectric particles. The step of admixing the linking element with the particle is inherently taught in the Parton references because Parton teaches that the oligonucleotide (a linking moiety/element) is bound to the surface to a polymer bead. This passage relates to the method of binding a microparticle (in this case is an oligonucleotide (linking element) to a polymer bead. Thus, the step of admixing the two elements together in a mixture is inherently taught. The oligonucleotide as a linking element must come into mixture with a the polymeric bead or particle in order to it to be bound on the polymer bead.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 571-272-0819. The examiner can normally be reached on Monday-Friday, 7:00-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pensee T. Do
Patent Examiner
August 2, 2006

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